Public Laws: 102nd Congress / Public Laws / 1991 and 1992

MEDICAL DEVICE AMENDMENTS OF 1992

Public Law 102-300
102d Congress

An Act

June 16, 1992
[S. 2783]

To amend the Federal Food, Drug, and Cosmetic Act with respect to medical devices and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Medical Device Amendments of 1992.
Safety.
21 USC 301 note.

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the "Medical Device Amendments of 1992".

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 2. EFFECTIVE DATE AND REGULATIONS TO IMPLEMENT DEVICE TRACKING.

(a) AMENDMENT.—Section 3 of the Safe Medical Devices Act of 1990 (21 U.S.C. 360i note) is amended—

(1) in subsection (b)(3), by striking out "upon the effective date" and inserting in lieu thereof "upon the expiration of 9 months after the issuance";

(2) in subsection (c)(2)—

(A) by striking out "and 519(e)" the first place it occurs; and

(B) by striking out "and 519(e) of such Act are" and inserting in lieu thereof "of such Act is"; and

(3) by adding at the end of subsection (c) the following: "(3) Not later than November 28, 1992, the Secretary shall issue final regulations to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations by November 28, 1992, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of section 519(e) of such Act is essential to protect the health of patients who use devices. In such event, the proposed regulations issued under paragraph (1) shall become the issued final regulations on November 29, 1992. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations.".

Federal Register, publication.

21 USC 360i note.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect as of May 27, 1992 and any rule to implement section 519(e) of the Federal Food, Drug, and Cosmetic Act proposed under section 3(c)(2) of the Safe Medical Devices Act of 1990 shall revert to its proposed status as of such date.

SEC. 3. POSTMARKET SURVEILLANCE.

(a) PROHIBITED ACT.—

(1) IN GENERAL.—Section 301(q)(1) (21 U.S.C. 331(q)(1)) is amended—

(A) by striking out "or (B)" and inserting in lieu thereof "(B)"; and

(B) by inserting before the period a comma and "or (C) comply with a requirement under section 522".

(2) MISBRANDED DEVICES.—Section 502(t) (21 U.S.C. 352(t)) is amended—

(A) by striking out "or (2)" and inserting in lieu thereof "(2)"; and

(B) by inserting before the period a comma and "or (3) to comply with a requirement under section 522".

(b) APPROVAL.—Section 522(b) (21 U.S.C. 360l(b)) is amended—

(1) by striking out "(a)" and inserting in lieu thereof "(a)(1)";

(2) by inserting a comma after "commerce"; and

(3) by adding after the first sentence the following: "Each manufacturer required to conduct a surveillance of a device under subsection (a)(2) shall, within 30 days after receiving notice that the manufacturer is required to conduct such surveillance, submit, for the approval of the Secretary, a protocol for the required surveillance.".

SEC. 4. REPAIR, REPLACEMENT, OR REFUND.

Section 518(b)(1)(A)(ii) (21 U.S.C. 360h(b)(1)(A)(ii)) is amended by striking out "and" each place it occurs and inserting in lieu thereof "or".

SEC. 5. REPORTING.

(a) AMENDMENTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) by redesignating paragraphs (1) through (6) of subsection (a) as paragraphs (4) through (9), respectively, and by inserting before paragraph (4) (as so redesignated) the following:

"(1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices—

"(A) may have caused or contributed to a death or serious injury, or

"(B) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;

"(2) shall define the term 'serious injury' to mean an injury that—

"(A) is life threatening,

"(B) results in permanent impairment of a body function or permanent damage to a body structure, or

"(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure;

"(3) shall require reporting of other significant adverse device experiences as determined by the Secretary to be necessary to be reported;"; and

(2) in subsection (b)—

(A) in paragraph (1), by striking out "there is a probability that a device has" each place it occurs and inserting in lieu thereof "a device has or may have";

(B) in paragraph (1)(B)—

(i) by striking out "aware of information" and inserting in lieu thereof "aware of—

"(i) information"; and

(ii) by striking out "facility, the facility" and inserting in lieu thereof: "facility, or

"(ii) other significant adverse device experiences as determined by the Secretary by regulation to be necessary to be reported,

the facility";

and

(C) in paragraph (5)(B)(iii), by striking out "immediate".

21 USC 360i note.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect—

(1) 1 year after the date of the enactment of this Act; or

(2) on the effective date of regulations of the Secretary to implement such amendments,

whichever occurs first.

SEC. 6. TECHNICALS.

(a) SECTION 201.—Section 201 (21 U.S.C. 321) is amended—

(1) in subsection (h), by striking out "any of its principal" and inserting in lieu thereof "its primary"; and

(2) by adding at the end the following:

"(ff) The term 'Commissioner' means the Commissioner of Food and Drugs.".

(b) REFERENCE.—

(1) Subsections (c) and (d) of sections 201, subsections (a), (d), (h), (i), (l), (m), and (o) of section 408, subsections (a) and (b) of section 536, section 701(b), and subsections (a) and (b) of section 801 (21 U.S.C. 321 (c) and (d), 346a (a), (d), (h), (i), (l), (m), and (o), 360mm (a) and (b), 371(b), and 381 (a) and (b)) and section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) are each amended by striking out "Health, Education, and Welfare" each place it appears and inserting in lieu thereof "Health and Human Services".

(2) Section 201(y), section 506(a), section 507(a), section 702(c), section 702A, and section 706(b)(5)(C)(i) (21 U.S.C. 321(y), 356(a), 357(a), 372(c), 372a, and 376(b)(5)(C)(i)) are each amended by striking out "of Health, Education, and Welfare" each place it appears.

(c) SECTION 304.—Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) by striking out "801(d)" each place it occurs and inserting in lieu thereof "801(e)"; and

(2) by striking out "clauses" and inserting in lieu thereof "paragraphs".

(d) SECTION 503.—Section 503(g)(3) (21 U.S.C. 353(g)(3)) is amended by striking out "approval" and inserting in lieu thereof "clearance".

(e) SECTION 513.—Section 513(f)(3) (21 U.S.C. 360c(f)(3)) is amended by redesignating clauses (i), (ii), and (iii) as subparagraphs (A), (B), and (C), respectively, and by striking out "the 510(k)" and inserting in lieu thereof "the section 510(k)".

(f) SECTION 517.—Section 517(a)(10) (21 U.S.C. 360g(a)(10)) is amended by striking out "520(c)(4)(B)" and inserting in lieu thereof "520(h)(4)(B)".

(g) SAFE MEDICAL DEVICES ACT OF 1990.—Section 18(b) of the Safe Medical Devices Act of 1990 is amended— 21 USC 360d.

(1) by striking out "(b)(4)(B)" and inserting in lieu thereof "(b)";

(2) in paragraph (1), by striking out "(3)" and inserting in lieu thereof "(4)"; and

(3) in paragraph (2), by striking out "(4)" and inserting in lieu thereof "(5)".

Approved June 16, 1992.

LEGISLATIVE HISTORY—S. 2783:

CONGRESSIONAL RECORD, Vol. 138 (1992):
May 21, considered and passed Senate.
May 28, considered and passed House.

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